AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 21

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	See Block 16C	OS268187	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

HOLOGIC INC. 193220
Attn: Jerry Wilson
10210 Genetic Center Dr
San Diego CA 92121

CODE 193220 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120P00100

10B. DATED *(SEE ITEM 13)* 08/04/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

Net Increase: $2,429,380.00

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: MUTUAL AGREEMENT OF THE PARTIES.
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 04-2902449
DUNS Number: 153623137
The purpose of this modification is to update the Statement of Work (Attachment 1) and to add supplemental funding to Line Item 2 in support of additional specimen collection needed for multiplex SARS-CoV-2/Flu assay; post-EUA testing of the multiplex SARS-CoV-2/Flu assay, additional work on shortening the lyo cycle, and improvements to the multi-tube system.

Attachment 1: Statement of Work (SOW) Revision 1

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.
Period of Performance: 08/04/2020 to 08/03/2021
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Karleen M. Oberton CFO	JEFFREY E. BROWN

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Karleen M. Oberton Karleen M. Oberton (Oct 23, 2020 05:55 EDT) *(Signature of person authorized to sign)*	Oct 29, 2020	Jeffrey E. Brown -S Digitally signed by Jeffrey E. Brown -S Date: 2020.10.29 14:41:07 -04'00' *(Signature of Contracting Officer)*	10/29/2020

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
HOLOGIC INC. 193220

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Change Item 1 to read as follows(amount shown is the obligated amount):				
1	ASPR-20-02979 -- Aptima SARS-CoV-2 Tests on Hologic Panther Systems Accounting Info: 2020.199C003.25106 Appr. Yr.: 2020 CAN: 199C003 Object Class: 25106 Funded: $0.00				0.00
	Add Item 2 as follows:				
2	ASPR-21-00082 -- additional funds to Base period of Hologic Inc contract 75A50120P00100 Accounting Info: 2021.199C023.25103 Appr. Yr.: 2021 CAN: 199C023 Object Class: 25103 Funded: $2,429,380.00				2,429,380.00

ATTACHMENT 1 – STATEMENT OF WORK

Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement BAA-20-100-SOL-0002

Improving COVID Test Supply and Assay Claims
Area of Interest #4.1 (COVID-19)

Statement of Work (SOW)

PREAMBLE

Independently, and not as an agent of the government, the Contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

OVERALL OBJECTIVES AND SCOPE

The purpose of this SOW is to ensure test availability, implement testing workflow improvements and gain Emergency Use Authorization (EUA) for a new SARS-CoV-2 assay that will help address the changing testing needs in the United States. As the COVID pandemic continues, priorities in the types of assays, performance claims and supply constraints for testing have changed. Currently, Hologic offers two assays for COVID testing, the Aptima SARS-CoV-2 assay and the Panther Fusion SARS-CoV-2 assay. Together these assays are used in more than 300 laboratories in the United States with monthly test volumes of over 4 million tests. Over time it has become apparent that even this supply of tests cannot meet the on-going demand for testing. The barriers to increasing availability of tests include many factors, including key consumables needed to run the tests as well as equipment to lyophilize the assay reagents.

For Hologic's assays, a key material limiting testing or expansion of testing is the availability of pipette tips compatible with the Panther system and the Panther Fusion system. As for equipment, the Aptima SARS-CoV-2 assay currently uses a lyophilization process that requires ~12 days per lot build and limits the number of tests that can be produced each month due to this build cycle. This SOW supports the evaluation of alternative suppliers for the pipette tips used for Hologic's COVID assays (Deliverable 2), and validation of a shorter lyophilization cycle for the Aptima SARS-CoV-2 assay (Deliverable 3). Through identifying and qualifying an

alternative supplier for pipette tips, Hologic will be able to better ensure that tests produced can be run by laboratories. Validation of a shorter lyophilization cycle could reduce the lot build cycle time to ~8 days and increase the average number of lot builds per month from ~2.5 to ~4. This statement of work will also include work to validate a shorter lyophilization cycle for the Aptima SARS-CoV-2/Flu multiplex assay (included as part of Deliverable 3).

In addition to improving test supply, how testing is performed is also limiting the number of tests that can be run each month. Currently, the Hologic assays are used for testing of individual samples from patients suspected of, or at risk for, SARS-CoV-2 infection. Recently, the FDA issued guidance to commercial manufacturers on how to validate assays for use with pooled samples. Testing sample pools allows more patient samples to be tested with fewer assay tests run overall. This SOW will include the validation and Emergency Use Authorization (EUA) submission of the Aptima SARS-CoV-2 and Panther Fusion SARS-CoV-2 assays for pooled samples (Deliverable 4). Once the EUA is granted, the assays will be able to be used by laboratories desiring to test pooled patient samples to expand the number of samples that can be tested. This SOW also includes work to integrate common third-party sample pooling instrumentation with the Panther system via the Panther Link software (Deliverable 5). This integration will enable identification of sample pools, allows for deconvoluting the results for pooled samples, and reporting results to a Laboratory Information System (LIS). This integration will make the complicated handling and reporting of pooled samples simpler, reduces risk of errors by improving traceability of results, and prepares Panther Link to support additional pooling instrumentation in the future.

As the United States is approaching its first full influenza season after the COVID-19 pandemic began, there will be a need for tests that help physicians differentiate between influenza and SARS-CoV-2 to help better manage patients and COVID-19 clusters. Therefore, this SOW will fund the transfer, validation, and Emergency Use submission/authorization of an Aptima SARS-CoV-2/Flu multiplex assay capable of detecting Flu A, Flu B and SARS-CoV-2 in a single test (Deliverable 6). The test will be a real-time Transcription-mediated Amplification (TMA) assay that will be capable of running on Panther and Panther Fusion systems with real-time fluorometers installed. It is anticipated that the Aptima SARS-CoV-2/Flu multiplex assay will be used in addition to or in lieu of the current SARS-CoV-2 assays and thus the validation of the new multiplex assay will include ensuring the assay can be produced at the same scale as the Aptima SARS-CoV-2 assay. Since the US testing needs and FDA requirements for a SARS-CoV-2/Flu multiplex assay may change over time, this statement of work will also include estimates for post-EUA activities as part of Deliverable 6.

This statement of work will include procurement of specimens for future clinical studies to evaluate the performance of the Aptima SARS-CoV-2/Flu assay to support FDA submissions to expand product claims or obtain an IVD clearance (Deliverable 7). This will be done by expanding efforts with current clinical sample suppliers supporting the efforts on Deliverable 4a of contract 75A50120P00069. In addition, the sample database setup as part of contract 75A50120P00069 will be leveraged for expedited and continued procurement of specimens.

Finally, this statement of work will include efforts to increase supply of the proprietary multi-tube unit (MTU) consumable used for every test run on the Panther System. The Hologic team will explore multiple options to increase supply and validate and implement at least one

option to improve supply of this constrained material.

The effort for **Improving COVID Test Supply and Assay Claims** will progress in work segments with key Deliverables being due during the Base Period of performance of the contract (the Base Period will be labeled Contract Line Item Number (CLIN) 0001). Each Deliverable will require a concrete work segment with a well-defined objective, scope of work, and success metric for accomplishing the Deliverable. The work segments for each Deliverable may occur sequentially or simultaneously based on the pathway and needs of the project.

The Deliverables for this project are described below:

1. **Deliverable 1** – Project Plan
2. **Deliverable 2** – Evaluation and Validation of alternative pipette tips
3. **Deliverable 3** – Validation of a shorter lyophilization cycle to reduce the build cycle time for the Aptima SARS-CoV-2 and Aptima SARS-CoV-2/Flu assays by a minimum of 20%
4. **Deliverable 4** – Obtain Emergency Use Authorization of pooled sample claims for the Hologic SARS-CoV-2 assays
5. **Deliverable 5** – Integration of sample pooling with Panther Link software
6. **Deliverable 6** – Obtain and expand Emergency Use Authorization for a real-time TMA SARS-CoV-2/Flu multiplex assay
7. **Deliverable 7** – Create specimen bank to be used for FDA submissions for the Aptima SARS-CoV-2/Flu assay
8. **Deliverable 8** – Validate and implement solution to increase supply of multi-tube units (MTUs) for COVID testing
9. **Deliverable 9** – Final Report and final data package

Deliverable 1: Project Plan

Objective:

Provide a detailed project plan outlining the goals, deliverables, and intended pathway for the project.

Scope of Work:

- Create Gantt Chart that identifies all goals and deliverables for the project
- Provide a description of the tools/techniques used to track and monitor the schedule and deliverables
- Provide a Risk Management Plan for the entire project
- Provide a regulatory plan for the entire project.

Success Metric for Completion of Deliverable 1:

- Provide all documentation to BARDA within 30 days of initiating the project
- BARDA acceptance of the files closes this milestone. Estimated cost: $25,000

Deliverable 2 – Evaluation and Validation of alternative pipette tips

Objective:

Identify alternatives to the sole-sourced capacitive level-sensing 1 mL pipette tips validated for use with the Hologic SARS-CoV-2 assays. Evaluate multiple alternative vendor options to determine candidates that match the performance criteria for the existing tip. Validate selected candidate tips to ensure better supply of tips for COVID testing.

Scope of Work:

- Create an Evaluation Plan
- Evaluate a minimum of 3 alternative tips
- Generate an Evaluation Summary Report identifying tips that meet performance criteria
- Create a Validation Plan
- Validate performance of tips that meet the performance criteria
- Generate a Validation Report
- Implement use of the validated tips for Hologic customer use

Success Metric for Completion of Deliverable 2:

- See Appendix 1 – Milestone 2 Deliverables and Success Criteria

Deliverable 3 – Validation of a shorter lyophilization cycle to reduce the build cycle time for the Aptima SARS-CoV-2 and Aptima SARS-CoV-2/Flu assays by a minimum of 20%

Objective:

Validate a shorter lyophilization cycle to reduce the build cycle time by a minimum of 20% for new lots of the Aptima SARS-CoV-2 assay

Scope of Work:

- Generate a Validation Plan for the new lyophilization cycle
- Complete lot builds for use for validation studies
- Generate a Validation Report
- Implement the lyophilization cycle for use in production of reagents for the Aptima SARS-CoV-2 and Aptima SARS-CoV-2/Flu assays

Success Metric for Completion of Deliverable 3:

- See Appendix 2 – Milestone 3 Deliverables and Success Criteria

Deliverable 4 – Obtain Emergency Use Authorization of pooled sample claims for the Hologic SARS-CoV-2 assays

Objective:

Obtain EUA for a pooled sample claim for the Hologic SARS-CoV-2 assays

Scope of Work:

- Work interactively with the FDA to establish validation testing requirements for a pooled sample claim
- Generate a Validation Plan for the pooled sample claim

- Obtain samples for validation studies
- Complete validation studies
- Generate a Validation Report
- Obtain Emergency Use Authorization from the FDA

Success Metric for Completion of Deliverable 4:

- See Appendix 3 – Milestone 4 Deliverables and Success Criteria

Deliverable 5 – Integration of sample pooling with Panther Link software

Objective:

Release an update to the Panther Link software that allows integration with common third-party sample pooling instrumentation to improve the sample pooling workflow for laboratories

Scope of Work:

- Update the Panther Link software requirements and specifications document to include sample pooling
- Generate a Validation Plan for the Panther Link software revision
- Revise the Panther Link software to implement new requirements and specifications
- Complete validation studies
- Generate a Validation Report
- Release the Panther Link software revision to customers using the pooled sample workflow for SARS-CoV-2 testing

Success Metric for Completion of Deliverable 5:

- See Appendix 4 – Milestone 5 Deliverables and Success Criteria

Deliverable 6: Obtain and expand Emergency Use Authorization for a real-time TMA SARS-CoV-2/Flu multiplex assay

Objective:

Obtain EUA for a real-time TMA-based SARS-CoV-2/Flu multiplex assay to provide a testing option to evaluate patients for both SARS-CoV-2 and Flu for the 2020/2021 Flu season in the United States.

Scope of Work:

- Work interactively with the FDA to confirm assay design, verification, and validation testing requirements for the multiplex assay
- Finalize verification and validation plans and acceptance criteria
- Complete Specification development, Verification and Validation studies to support EUA submission
  a. Establish analytical sensitivity
  b. Establish specificity and lack of cross reactivity with other potentially reactive organisms, including other coronaviruses
  c. Execute guard banding studies to establish tolerance limits for manufacturing
  d. Create verification panels using inactivated virus spiked into clinical matrix, and

with clinical specimens obtained from external laboratories
e. Complete verification studies to confirm assay sensitivity, specificity, and reproducibility
f. Establish performance claims for clinical specimens
g. Develop process controls and lock software parameters

- Transfer existing assay design to Operations
- Validate manufacturing processes
- Finalize all study reports
- Obtain Emergency Use Authorization from the FDA
- Complete any post-authorization studies required by the FDA or to support expanded US testing needs

Success Metric for Completion of Deliverable 6:

- See Appendix 5 – Milestone 6 Deliverables and Success Criteria

Deliverable 7 – Create specimen bank to be used for FDA submissions for the Aptima SARS-CoV-2/Flu assay

Objective:
Prospectively obtain positive and negative clinical respiratory specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Specimens can be used to support FDA submissions for the Aptima SARS-CoV-2/Flu assay.

Scope of Work:

- Execute contract amendments with sample suppliers for continued procurement, including IRB, if needed
- Monitor procurement of specimens
- Update database to allow for the collection of standard-of-care respiratory testing assay and results (i.e., Influenza A, Influenza B)
- Document specimen attributes such as demographics, date of collection, standard of care respiratory testing assay and results
- Store specimens for use in upcoming studies

Success Metric for Completion of Deliverable 7:

- See Appendix 6 – Milestone 7 Deliverables and Success Criteria

Deliverable 8 – Validate and implement solution to increase supply of multi-tube units (MTUs) for COVID testing

Objective:
Evaluate options, validate and implement a solution to increase supply of MTUs for COVID testing

Scope of Work:

- Identify feasible option to increase MTU supply, which can include increasing production output or implementing alternative approaches to increase MTU supply
- Complete builds for use for validation studies
- Generate a Validation Report
- Implement the increased MTU production solution and make material available for sale

Success Metric for Completion of Deliverable 8:

- See Appendix 7 – Milestone 8 Deliverables and Success Criteria

Deliverable 9: Final Report and Final Data Package

Objective:

Complete and deliver all outstanding documentation and data to BARDA

Scope of Work:

- Complete final study report and documentation

Success Metric for Completion of Deliverable 9:

- Final report to include a summation of the work performed and results obtained for the entire contract period of performance.

- Final data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.

PROGRAM MANAGEMENT

The Contractor shall provide the following as outlined below:

a) The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities.

b) A Principal Investigator (PI) or Project Manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modifications to the project requirements, deliverables and timelines, including projects undertaken by subcontractors.

c) A PM with responsibility for monitoring and tracking day-to-day progress and timelines of deliverables, coordinating communication and project activities, costs incurred, and program management.

d) A BARDA liaison (may be the PM) with responsibility for effective communication with the

Contracting Officer (CO), Contract Specialist (CS), and Contracting Officer's Representative (COR).

e) Administrative and legal staff capable of developing compliant subcontracts, consulting, and other legal agreements, while also ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights and reporting all inventions made in the performance of the contract.

f) Administrative staff capable of financial management and reporting on all activities conducted by the Contractor and any subcontractors.

g) Contract Review Meetings

The Contractor shall participate in regular meetings to coordinate and oversee the contract effort jointly with the CO, CS, and COR. Such meetings may include, but are not limited to, the following:

- Meeting with the Contractor and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assay development, preclinical/clinical study designs and regulatory issues.

- Meeting with individual government consultants and other government officials to discuss the technical, regulatory, and ethical aspects of the program.

- Meeting with technical consultants to discuss technical data provided by the Contractor.

h) The Contractor shall participate in teleconferences every week with the CO, CS and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be less frequent at the direction of the CO.

i) Gantt Chart

Within 30 calendar days of the effective date of the contract, the Contractor shall submit a first draft of an updated Gantt Chart to the CO, CS and COR for review. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance. The Contractor shall include the key milestones, deliverables, and Go/No-Go decision gates.

j) Project Management Plan

In the management of this contract, the Contractor is encouraged to utilize Project Management tools/techniques to track and monitor the cost and schedule of the project. The Contractor and the government agree that at a minimum, the Contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes.

k) Risk Management Plan

The Contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems or issues that may arise during the life of the contract, including the impact on cost, schedule, and performance. Appropriate remediation plans should reference relevant work segments where appropriate. Updates to this plan shall be included, at a minimum, on a quarterly basis (every three months) in the monthly Project Status Report.

l) Monthly and Annual Reports

If requested, the Contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW or other Project Management Plan tool(s):

- Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities.
- Progress in meeting contract deliverables, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps.
- Updated Risk Management Plan (every 3 months).
- Three-month rolling forecast of planned activities.
- Progress of regulatory submissions.

m) Data Management

The Contractor shall:

- Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data.
- Provide for the statistical design and analysis of data resulting from the research.
- Provide raw data or specific analyses of data generated with contract funding to the CO, CS, and COR, upon request.

REGULATORY

The Contractor shall perform the following as outlined below:

a) Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication.

b) Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages.

c) Provide BARDA with (1) initial draft minutes and final draft minutes of any formal meeting with the FDA, and (2) final draft minutes of any informal meeting with the FDA.

d) Provide all communications with FDA to BARDA.

e) Provide a regulatory plan.

FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Contractor shall provide equipment, facilities, and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

a) The humane care and use of vertebrate animals.

b) The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study.

Appendix 1 – Milestone 2 Deliverables and Success Criteria

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
2. Evaluation and Validation of alternative pipette tips				
2.1	Complete Evaluation Plan for the evaluation of pipette tips	Provide BARDA with an Evaluation Plan (EP) covering the test methods and studies to be performed to evaluate pipette tips. BARDA acceptance of the EP closes this milestone.	August 2020	$12,000
2.2	Complete Evaluation of at least 3 pipette tips and an Evaluation Report	Complete evaluation studies on a minimum of 3 pipette tips and summarize results identifying acceptable tips in an Evaluation Report (ER). Provide BARDA with the ER. BARDA acceptance of the ER closes this milestone.	August 2020	$50,000
2.3	Complete Validation Plan for validation of one or more new pipette tips	Provide BARDA with a Validation Plan (VP) describing the validation study plan for testing pipette tips. BARDA acceptance of the VP closes this milestone.	August 2020	$25,000
2.4	Complete Master Validation Report for the pipette tip testing	Provide BARDA with a Validation Report (VR) documenting the completion of the validation studies for the pipette tips. BARDA acceptance of the VR closes this milestone.	October - December 2020	$300,000
2.5	Implement the validated tips in Hologic instructions for use allowing customers to use the tips	Provide BARDA with Hologic product labeling (IFU, customer technical bulletin, or other) indicating the pipette tips are acceptable for use. BARDA acceptance of the product labeling closes this milestone.	October - December 2020	$25,000

Appendix 2 – Milestone 3 Deliverables and Success Criteria

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
3. Validation of a shorter lyophilization cycle to reduce the build cycle time for the Aptima SARS-CoV-2 and Aptima SARS-CoV-2/Flu **assays by a minimum of 20%**				
3.1	Complete Validation Plan for the new lyophilization cycle	Provide BARDA with a Validation Plan (VP) describing the validation study plan for the new lyophilization cycle. BARDA acceptance of the VP closes this milestone.	August 2020	$25,000
3.2	Complete lot builds for validation testing	Provide BARDA with a summary of the lot builds produced to support validation of the shorter lyophilization cycle. BARDA acceptance of the lot build summary closes this milestone.	September 2020	$450,000
3.3	Complete Master Validation Report for the shorter lyophilization cycle	Provide BARDA with a Validation Report (VR) documenting the completion of validation studies for the shorter lyophilization cycle. BARDA acceptance of the VR closes this milestone.	September 2020	$50,000
3.4	Implement the shorter lyophilization cycle into production for the Aptima SARS-CoV-2 assay	Provide BARDA with a summary documenting the implementation of the shorter lyophilization cycle into production and demonstrating reduction in minimum build cycle time for the Aptima SARS-CoV-2 assay. BARDA acceptance of the summary documentation closes this milestone.	October 2020	$25,000
3.5	Complete Validation Plan for the Aptima SARS-CoV-2/Flu new lyophilization cycle	Provide BARDA with a Validation Plan (VP) describing the validation study plan for the Aptima SARS-CoV-2/Flu new lyophilization cycle. BARDA acceptance of the VP closes this milestone.	January 2021	$10,000
3.6	Complete lot builds for the Aptima SARS-CoV-2/Flu validation testing	Provide BARDA with a summary of the Aptima SARS-CoV-2/Flu lot builds produced to support validation of the shorter lyophilization cycle. BARDA acceptance of the lot build summary	March 2021	$300,000

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
		closes this milestone.		
3.7	Complete Master Validation Report for the Aptima SARS-CoV-2/Flu assay shorter lyophilization cycle	Provide BARDA with a Validation Report (VR) documenting the completion of validation studies for the Aptima SARS-CoV-2/Flu assay shorter lyophilization cycle. BARDA acceptance of the VR closes this milestone.	April 2021	$30,000
3.8	Implement the shorter lyophilization cycle into production for the Aptima SARS-CoV-2/Flu assay	Provide BARDA with a summary documenting the implementation of the shorter lyophilization cycle into production and demonstrating reduction in minimum build cycle time for the Aptima SARS-CoV-2 assay. BARDA acceptance of the summary documentation closes this milestone.	May 2021	$15,000

Appendix 3 – Milestone 4 Deliverables and Success Criteria

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
4. Obtain Emergency Use Authorization of pooled sample claims for the Hologic SARS-CoV-2 assays				
4.1	Complete Validation Plan for the pooled sample claim	Provide BARDA with a Validation Plan (VP) describing the validation study plan for the pooled sample claim. BARDA acceptance of the VP closes this milestone.	August 2020	$25,000
4.2	Complete Validation Report for the pooled sample claim	Provide BARDA with a Validation Report (VR) documenting the completion of validation studies for the pooled sample claim. BARDA acceptance of the VR closes this milestone.	August 2020	$275,000
4.3	Submit EUA amendment to add pooled sample claim	Provide BARDA with Emergency Use Authorization notification from the FDA for the pooled sample claims. BARDA acceptance of the EUA notification closes this milestone.	August 2020	$30,000

Appendix 4 – Milestone 5 Deliverables and Success Criteria

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
5. Integration of sample pooling with Panther Link software				
5.1	Create the SRS for pooled sample integration with Panther Link	Provide BARDA with the SRS document describing the requirements and specifications for sample pooling. BARDA acceptance of the SRS closes this milestone.	August 2020	$25,000
5.2	Complete Validation Plan for the pooled sample integration with Panther Link	Provide BARDA with a Validation Plan (VP) describing the validation study plan to test the Panther Link software revision. BARDA acceptance of the VP closes this milestone.	August 2020	$50,000
5.3	Complete Validation Report for the pooled sample integration with Panther Link	Provide BARDA with a Validation Report (VR) documenting the completion of validation studies testing the Panther Link software revision. BARDA acceptance of the VR closes this milestone.	December 2020	$1,760,000
5.4	Release the Panther Link software revision	Provide BARDA with evidence of release of the Panther Link software revision. BARDA acceptance of the evidence of software release closes this milestone.	December 2020	$150,000

Appendix 5 – Milestone 6 Deliverables and Success Criteria

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
6. Obtain and expand **Emergency Use Authorization for a real-time TMA SARS-CoV-2 multiplex assay**				
6.1	Complete quality specification development	Provide BARDA with a Quality & Specification report summarizing the test specifications for QC testing of the Aptima SARS-CoV-2/Flu multiplex assay. BARDA acceptance of the report closes this milestone.	October 2020	$510,000
6.2	Completion of lot builds to support V&V testing	Provide BARDA with a summary demonstrating completion of 2 lot builds of Amp, Enzyme, Probe and Target Capture reagents for use in Verification and Validation of the assay. BARDA acceptance of the summary closes this milestone.	October 2020	$1,250,000
6.3	Completion of Design Input/System Integration	Provide BARDA with the System Integration Design Review documentation summarizing completion of development activities to demonstrate that the assay performs on the system and process controls have been established for the assay. BARDA acceptance of the documentation closes this milestone.	September 2020	$1,300,000
6.4	Complete setup of manufacturing parts	Provide BARDA with a summary documenting the completion of production level part creation for the Aptima SARS-CoV-2/Flu multiplex assay. BARDA acceptance of the summary closes this milestone.	October 2020	$450,000
6.5	Completion of Assay, Software and System V&V	Provide BARDA with V&V reports summarizing the completion of verification and validation activities to support EUA submission. BARDA acceptance of the reports closes this milestone.	November 2020	$1,850,000
6.6	EUA submission of the Aptima SARS-CoV-2/Flu multiplex assay to the FDA	Provide BARDA with the completed FDA EUA submission files for the Aptima SARS-CoV-2/Flu multiplex assay. BARDA acceptance of the files closes this milestone.	November 2020	$250,000
6.7	Completion of post-authorization studies for the Aptima SARS-CoV-2/Flu multiplex assay	Provide BARDA with FDA post-authorization study requirements, study completion and submission documentation. BARDA acceptance of the files closes this milestone.	June 2021	$400,000
6.8	Completion of studies and	Provide BARDA with the completed FDA EUA amendment	June 2021	$250,000

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
	EUA amendment submission for claim expansion for the Aptima SARS-CoV-2/Flu assay	submission files for claim expansion studies completed for the Aptima SARS-CoV-2/Flu assay.		

Appendix 6 – Milestone 7 Deliverable and Success Criteria Amendment

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing[1]	Estimated Cost
7. Create specimen bank to be used for FDA submissions for the Aptima SARS-CoV-2/Flu assay				
7.1	Create specimen bank to be used for FDA submission	Provide BARDA with a summary of contract amendments with sites for the collection/handling of clinical samples. BARDA acceptance of the summary closes this milestone.	November 2020	$40,000
7.2	Receive and Database Samples	Provide summary to BARDA documenting collection of 300 total samples. BARDA acceptance of the summary closes this milestone.	November 2020	$126,340
7.3	Receive and Database Samples	Provide summary to BARDA documenting collection of 600 total samples. BARDA acceptance of the summary closes this milestone.	December 2020	$126,340
7.4	Receive and Database Samples	Provide summary to BARDA documenting collection of 900 total samples. BARDA acceptance of the summary closes this milestone.	January 2021	$126,340
7.5	Receive and Database Samples	Provide summary to BARDA documenting collection of 1,200 total samples. BARDA acceptance of the summary closes this milestone.	February 2021	$126,340
7.6	Receive and Database Samples	Provide summary to BARDA documenting collection of 1,500 total samples. BARDA acceptance of the summary closes this milestone.	March 2021	$126,340
7.7	Receive and Database samples	Provide summary to BARDA documenting collection of 1,800 total samples. BARDA acceptance of the summary closes this milestone.	April 2021	$126,340
7.8	Receive and Database samples	Provide summary to BARDA documenting collection of 2,100 total samples. BARDA acceptance of the summary closes this milestone.	May 2021	$126,340

[1] The timeline for collection reflects the highest expected prevalence for seasonal Influenza in the US. The majority of specimens will be procured from the US; some specimens may be procured in Australia or New Zealand, which has a different influenza season than the US, typically running from April to October.

Appendix 7 – Milestone 8 Deliverables and Success Criteria

Milestone #	Milestone	Deliverable/Success Criteria	Estimated Timing	Estimated Cost
8. Validate and implement solution to increase supply of multi-tube units (MTUs) for COVID testing				
8.1	Complete Validation Plan for the MTU production expansion option	Provide BARDA with a Validation Plan (VP) describing the validation study plan for the MTU production expansion option. BARDA acceptance of the VP closes this milestone.	November 2020	$25,000
8.2	Complete Master Validation Report for MTU production expansion option	Provide BARDA with a Validation Report (VR) documenting the completion of validation studies for the MTU production expansion option. BARDA acceptance of the VR closes this milestone.	January 2021	$450,000
8.3	Implement the MTU production expansion option into production	Provide BARDA with a summary documenting the implementation of the MTU production expansion option into production and demonstrating increased production capacity. BARDA acceptance of the summary documentation closes this milestone.	February 2021	$25,000

*** End of Document ***